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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,173

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EXAMINER

ORWIG, KEVIN S

ART UNIT

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1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,173	Applicant(s) HASHIMOTO ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/5/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

Claims 1-7 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be May 7, 2004, the filing date of PCT application PCT/JP04/06024 to which the instant national stage 371 application claims priority. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Japanese application was filed with the USPTO on Oct. 5, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuruda *et al.* (International Patent Application Publication No. WO 01/68061; Published Sep. 20, 2001; Reference BA on IDS dated Oct. 5, 2005) as evidenced

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by Tsuruda *et al.* (U.S. Patent No. 6,924,410; Issued Aug. 2, 2005) (hereinafter Tsuruda *et al.*).

1. Since the WO publication is in Japanese, the U.S. patent to Tsuruda *et al.*, which is the result of the national stage entry of the international application, is relied upon herein as an English language equivalent for all rejections based on WO 01/68061. Column and line numbers refer to the '410 patent.

2. Tsuruda *et al.* disclose an ultraviolet-screening type patch comprising an organic ultraviolet (UV) absorbent and an inorganic UV screening agent (abstract). Tsuruda *et al.* teach that the patch of their invention may comprise a polyester backing (column 4, lines 38-41) and an adhesive base (i.e. a pressure-sensitive adhesive) (column 5, lines 44-50) on a surface of the backing layer (column 4, lines 34-37). Tsuruda *et al.* teach that the adhesive base may contain ketoprofen, which is a nonsteroidal anti-inflammatory drug (NSAID) (column 2, lines 38-41; column 11, lines 25-43; column 13, lines 3-17, Formulation 4; claim 1). Furthermore, Tsuruda *et al.* teach that the backing may comprise a benzotriazole derivative such as that represented by the general formula (1) in instant claim 1 (column 2, lines 42-57, especially lines 50-52; claim 6). Thus, Tsuruda *et al.* anticipates instant claims 1 and 5.

3. Tsuruda *et al.* teach that the backing may contain titanium oxide (column 2, lines 20-33; claim 3), reading on instant claim 2.

4. Tsuruda *et al.* teach that the adhesive base may comprise a styrene-isoprene-styrene block copolymer or polyisobutylene (column 7, lines 7-14; claim 9), reading on claim 6.

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5. Tsuruda *et al.* teach that there is no need to add a UV absorbent into the base (i.e. adhesives) of their invention (column 11, lines 60-61, and Formulas 1-4 in columns 12 and 13), reading on instant claim 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda *et al.*

7. Tsuruda *et al.* teach the patch of instant claim 1 as discussed above. Tsuruda *et al.* teach that the light transmittance of their patch is preferably not more than 15% under the condition of a UV intensity being about 0.14 mW/hr/cm² (column 4, lines 25-

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26). Additionally, Tsuruda *et al.* teach that the phototransmission rate for their patches may be 2.0% or less (Table 1).

8. While it is not clear that the phototransmission taught by Tsuruda *et al.* is equivalent to the ultraviolet transmittance of instant claim 3, the two parameters are measured in an essentially identical fashion. For instance, in paragraph [0036] the instant specification states, "As for the calculation of the ultraviolet transmittance, an ultraviolet dose transmitting through the backing is measured under a circumstance in which a direct sunlight irradiates enough to the backing, and the ultraviolet intensity without the above preparation is made 100, calculating each transmittance." By comparison, Tsuruda *et al.* teach irradiating a backing with sunlight to observe the UV intensity and then calculating the phototransmission rate of the backing on the basis of the UV intensity. Thus, based on the evidence and reasoning presented above, it is the examiner's position that the backings of Tsuruda *et al.* would have a UV transmittance of not more than 2%.

9. Since Tsuruda *et al.* teach the same compound in the backing layer, the functional limitation is considered inherent because the prior art structure is substantially identical to that of the claimed invention. The MPEP states that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant

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has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP § 2112.01.

Claims 1, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda *et al.* in view of Cordes *et al.* (International Publication WO 97/232227, published Jul. 3, 1997) (hereinafter Cordes *et al.*).

10. Tsuruda *et al.* teach the patch of instant claim 1 as discussed above. Regarding claim 4, Tsuruda *et al.* teach that polyester cloth is preferably used as the backing because it has a good feel and usage sense and that these materials preferably have a mass of 70-130 g/cm² (column 10, lines 15-24). It is noted that instant claim 4 recites, "...wherein the weight of the backing is 100 g/m²-130 g/m²."

11. Since both Tsuruda *et al.* and the instant application teach essentially the same invention, it is the examiner's position that the teaching of 70-130 g/cm² by Tsuruda *et al.* is a typographical error and that one of ordinary skill in the art would readily have recognized this error, which should be 70-130 g/m². It is noted that similar polyester layers have weights per area on the order of 100 g/m² (see obviousness rejection below). In further support of this position is the fact that both Tsuruda *et al.* and the instant specification teach polyester cloth as the backing material (see Tsuruda *et al.* column 10, line 15 and paragraph [0034] of the instant specification). Since there is a difference of *four orders of magnitude* between the units of g/cm² and g/m², it is reasonable to expect that one of these measurements is in error and that the same backing material for essentially the same invention (a UV-shielding skin patch) would not have a weight per area range this large. Furthermore, example 1 of the instant

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application states that a polyester woven fabric was used that had a weight of about 110 g/cm². Either this is a similar typographical error, or it is evidence that the material used by Tsuruda *et al.* would meet the limitations of claim 4.

12. Nonetheless, one of ordinary skill in the art would have envisaged the use of a polyester backing having a weight per area of between 100 and 130 g/m² since patches using polyester backings of this type were known in the art at the time of the invention. For instance Cordes *et al.* disclose a transdermal patch having a polyester backing layer with a weight per area of 96 ± 5 g/m². Since Tsuruda *et al.* teach that a patch having a backing that is too thick or thin is undesirable, the ordinary artisan would have turned to the literature for additional guidance about what weights/thicknesses of material had been used successfully in the past. Thus, in light of the disclosure of Cordes *et al.*, it would have been *prima facie* obvious for the ordinary artisan to produce the patch taught by Tsuruda *et al.* with a polyester backing of about 100 g/m² as taught by Cordes *et al.*, reading on instant claim 4.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application No. 10/584,739

10. Claims 1, 2, 5, and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/584,739. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '739 claims anticipates or renders obvious that of the instant claims. Most elements of instant claim 1 are anticipated by the '739 application. For instance, claim 1 of the '739 application recites a patch comprising a support and an adhesive base comprising an NSAID and a UV blocking agent or agents. The overall scope of the claims is not *anticipated* because the claims of the '739 application do not recite that the support (i.e. the backing) be polyester and do not recite the specific benzotriazole derivative represented by formula (1) in instant claim 1. However, this element, and thus the entire scope of the instant claims is rendered obvious since, polyester backings are commonly used in such adhesive patches (see the discussion above in paragraph 11 where Cordes *et al.* uses a polyester backing). Furthermore, '739 claims 4 and 5 recite hydroxyphenylbenzotriazole derivatives. While a specific derivative corresponding to formula (1) is not recited, such compounds are known UV absorbing agents and inclusion of a compound of formula (1) given the teaching of hydroxyphenylbenzotriazole derivatives is an obvious variation.

U.S. Patent No. 6,924,410

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Claims 1, 2, 5, and 6 are non-provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6, and 9 of U.S. Patent No. 6,924,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '410 claims anticipates or renders obvious that of the instant claims. While most elements of instant claim 1 are anticipated by the '410 application, the overall scope of the claims is not anticipated because the claims of the '410 application do not recite a polyester backing and do not recite a specific benzotriazole derivative. However, these elements, and thus the entire scope of the instant claims is rendered obvious since, polyester backings are commonly used in such adhesive patches (see the discussion above in paragraph 11 where Cordes *et al.* uses a polyester backing). Furthermore, '410 claim 6 recites benzotriazole derivatives. While a specific derivative corresponding to formula (1) is not recited, such compounds are known UV absorbing agents and inclusion of a compound of formula (1) given the teaching of benzotriazole derivatives is an obvious variation.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-

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5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611